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ATTORNEY DOCKET NO.: 0492611-0383

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Madry, *et al.* Examiner:
Serial No.: 09/809,456 Art Unit: 3739
Filing Date: March 15, 2001
Title: TISSUE ENGINEERING ENHANCED BY THE TRANSFER OF A
GROWTH FACTOR GENE

Assistant Commissioner for Patents
Washington, DC 20231

**COPY OF PAPERS
ORIGINALLY FILED**

Sir:

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS

**37 CFR 1.9(f) and 1.27(c)
SMALL BUSINESS CONCERN**

I hereby declare that I am

- () the owner of the small business concern identified below:
(X) an official empowered to act on behalf of the small business concern identified below:

NAME OF CONCERN: Massachusetts Institute of Technology
ADDRESS OF CONCERN: 5 Cambridge Center - Kendall Square, Room NE25-230,
Cambridge, MA 02142-1493

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For the purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full time, part time, or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when, either directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract of law have been conveyed to and remain with the small business concern identified above with regard to the invention titled:

TITLE: TISSUE ENGINEERING ENHANCED BY THE TRANSFER OF A GROWTH FACTOR GENE

INVENTOR(S): Henning Madry, Gordana Vunjak-Novakovic, Stephen B. Trippel, Lisa Freed, and Robert Langer

described in:

() the specification filed herewith
(X) U.S. Patent Application Serial Number 09/809,456
filed March 15, 2001
() U.S. Patent Number _____
issued _____

If the rights of the above-identified small business concern are not exclusive, each individual, concern, or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor(s), who could not qualify as a small business concern under 37 CFR 1.9(d) or a non-profit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern, or organization having rights to the invention, averring to their status as small entities. (37 CFR 1.27).

FULL NAME:

ADDRESS:

() INDIVIDUAL () SMALL BUSINESS CONCERN () NON-PROFIT ORGANIZATION

FULL NAME:

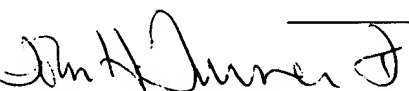
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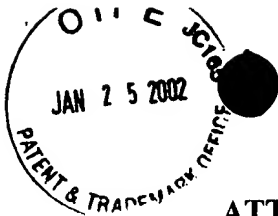
() INDIVIDUAL () SMALL BUSINESS CONCERN () NON-PROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: JOHN H. TURNER, JR.
TITLE IN ORGANIZATION: ASSOCIATE DIRECTOR
ADDRESS OF PERSON SIGNING: TECHNOLOGY LICENSING OFFICE
77 Massachusetts Avenue
Cambridge, MA 02139 USA

SIGNATURE:  DATE: 5 June 2001



ATTORNEY DOCKET NO.: 0492611-0383

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Madry, *et al*

Examiner:

Serial No.: 09/809,456

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Title: TISSUE ENGINEERING ENHANCED BY THE TRANSFER OF A
GROWTH FACTOR GENE

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

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APPOINTMENT OF ATTORNEY

The undersigned hereby appoints Brenda Herschbach Jarrell, Registration No. 39,223; Sam Pasternack, Registration No. 29,576; Kevin M. Tormey, Registration No. 41,351; Karoline K.M. Shair, Registration No. 44,332; Elizabeth E. Nugent, Registration No. 43,839; Anne-Marie Dinius, Registration No. 45,592; Valarie B. Rosen, Registration No. 45,698; Stanley C. Mah, Registration No. 46,189; C. Hunter Baker, Registration No. 46,533; Monica Gerber, Registration No. 46,724; Elijah Cocks, Registration No. 47,499, and Mika Mayer, Registration No. 47,777 as its attorneys and agents for prosecution of matters relating to the above-identified patent application and to conduct all business in the United States Patent and Trademark Office.

All correspondence should be sent to Valarie B. Rosen, Choate, Hall & Stewart, Exchange Place, 53 State Street, Boston, Massachusetts 02109.

Respectfully submitted,

Name: JOHN H. TURNER, JR.
Title: ASSOCIATE DIRECTOR
TECHNOLOGY LICENSING OFFICE
Date:

ATTORNEY DOCKET NO.: 0492611-0383

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Madry, *et al*

Examiner:

Serial No.: 09/809,456

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Title: TISSUE ENGINEERING ENHANCED BY THE TRANSFER OF A
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Assistant Commissioner for Patents
Washington, DC 20231

Sir:

ESTABLISHING RIGHT OF ASSIGNEE TO TAKE ACTION (37 CFR 3.73(b))

The assignee of the entire right, title and interest, **Massachusetts Institute of Technology** hereby seeks to take action in the Patent and Trademark Office in the above matter.

Ownership by the assignee is established as follows:

_____ documents already recorded in the PTO on _____.

Reel _____ Frame _____; and

Reel _____ Frame _____

 X documents separately submitted for recordal to the PTO (a copy of these documents is attached).

09809456-012502

STATEMENT

I, a person authorized to sign on behalf of the assignee, have reviewed the evidentiary documents referred to above and certify that, to the best of my knowledge and belief, title is mine/ours as assignee who seeks to take further action.



Signature

Name JOHN H. TURNER, JR.
ASSOCIATE DIRECTOR
TECHNOLOGY LICENSING OFFICE

Title

Date 5 June 2001

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Attorney Docket Number 0492611-0383

DECLARATION

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As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TISSUE ENGINEERING ENHANCED BY THE TRANSFER OF A GROWTH FACTOR GENE

the specification of which (I authorize Choate, Hall & Stewart to check one of the following, three choices, and fill in the blanks, if applicable):

___ is attached hereto

X was filed on March 15, 2001 as Application Serial No. 09/809,456 and amended on _____ (if applicable).

___ was filed as PCT international application No. _____, on _____ and was amended under PCT Article 19 on _____ (if applicable).

I hereby state that I have reviewed and understood the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledged the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

Priority Claimed

(Number)	(Country)	(Day/Month/Year/Filed)	Yes	No
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_____ (Number)	_____ (Country)	_____ (Day/Month/Year/Filed)	_____ Yes	_____ No
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09809456-012502

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

<u>(Application Serial No.)</u>	<u>(filing date)</u>	<u>(status-patented, pending, abandoned)</u>
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PCT Applications designating the United States:

<u>(PCT Appl. No.)</u>	<u>(U.S.S.N.)</u>	<u>(status-patented, pending, abandoned)</u>
------------------------	-------------------	--

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national filing date of this application.

Provisional Application(s):

<u>(Application Serial No.)</u>	<u>(filing date)</u>	<u>(status-patented, pending, abandoned)</u>
---------------------------------	----------------------	--

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

00000456 012502

1) Full name of first inventor: Henning Madry

Inventor's signature: Henning Madry Date: 8/28/01

Residence: VOLHARDSTR. 7, 66424 HOMBURG, GERMANY

Citizenship: GERMANY

Post Office Address: EISENBAHNSTR. 1, 06217 MERSEBURG
GERMANY

2) Full name of second inventor: Gordana Vunjak-Novakovic

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

3) Full name of third inventor: Stephen B. Trippel

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

4) Full name of second inventor: Lisa Freed

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

5) Full name of third inventor: Robert Langer

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

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1) Full name of first inventor: Henning Madry

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

2) Full name of second inventor: Gordana Vunjak-Novakovic

Inventor's signature: *G. Vunjak* Date: 7/14/01

Residence: 305 FITZMAURICE CIRCLE, BELMONT MA 02478

Citizenship: US

Post Office Address: _____

3) Full name of third inventor: Stephen B. Trippel

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

4) Full name of second inventor: Lisa Freed

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

5) Full name of third inventor: Robert Langer

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

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1) Full name of first inventor: Henning Madry
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

2) Full name of second inventor: Gordana Vunjak-Novakovic
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

3) Full name of third inventor: Stephen B. Trippel
Inventor's signature: Stephen Trippel Date: 7/26/01
Residence: 59 Woodland Rd, Auburndale, MA 02117
Citizenship: USA
Post Office Address: Dept. of Orthopaedics, IUSM, 541 Clinical Drive, Suite 600, Indianapolis, IN, 46202

4) Full name of second inventor: Lisa Freed
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

5) Full name of third inventor: Robert Langer
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

1) Full name of first inventor: Henning Madry

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

2) Full name of second inventor: Gordana Vunjak-Novakovic

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

3) Full name of third inventor: Stephen B. Trippel

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

4) Full name of second inventor: ^{E.} Lisa Freed

Inventor's signature: Lisa E. Freed Date: 7/19/01

Residence: 34 Palfrey Rd. Belmont, MA 02478

Citizenship: USA

Post Office Address: —

5) Full name of third inventor: Robert Langer

Inventor's signature: _____ Date: _____

Residence: _____

Citizenship: _____

Post Office Address: _____

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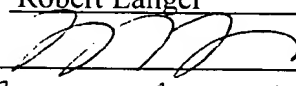
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1) Full name of first inventor: Henning Madry
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

2) Full name of second inventor: Gordana Vunjak-Novakovic
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

3) Full name of third inventor: Stephen B. Trippel
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

4) Full name of second inventor: Lisa Freed
Inventor's signature: _____ Date: _____
Residence: _____
Citizenship: _____
Post Office Address: _____

5) Full name of third inventor: Robert Langer
Inventor's signature:  Date: 10/1/01
Residence: 93 Montvale Rd, Newton MA 02459
Citizenship: 7/3
Post Office Address: _____